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APPLICATION FOR LETTERS PATENT

for

SYSTEM, METHOD AND PACKAGE FOR PROVIDING A SUCROSE SOLUTION

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SYSTEM, METHOD AND PACKAGE FOR PROVIDING A SUCROSE SOLUTION

BACKGROUND OF THE INVENTION

Field of the Invention: The present invention relates to providing a sucrose solution having demonstrated analgesic and calming effects for use with neonatal infants and, more specifically, a system, method and package for providing such solutions in prepackaged, sterile form.

State of the Art: All newborn infants are subjected to a variety of medical procedures after birth. Such procedures include, by way of example only, vitamin K injections, immunization, circumcision, and venipuncture or heel stick for blood sampling. Preterm or ill infants experience additional, often painful and stressful, diagnostic procedures and treatments. However, only in rare instances do neonatal infants receive prophylactic analgesia.

Neonatal infants demonstrate a preference for sweet tasting substances, including sucrose, fructose and glucose as well as artificial sweeteners. Intake of sucrose has demonstrated analgesic and calming effects on infants, and the other substances previously mentioned may have similar effects, but this has not been proven. On the other hand, lactose apparently does not induce analgesia or calming effects in newborn infants. Moreover, administration of oral sucrose has been proven to promote increased sucking and hand-to-mouth behavior in infants as well as reducing crying-related energy expenditure, the absence of which may positively affect feeding behavior and growth. No published studies of the analgesic or calming effect of dextrose are known to the inventor.

Current practice in hospitals employing substances such as sucrose, dextrose or even common table sugar is to mix up a large batch of solution in an on-site kitchen or pharmacy. As noted above, sucrose is the only sugar recognized uniformly to provide the desired analgesic and calming effects so, in some instances, administration of a sweet solution to infants is not efficacious. Moreover, the conditions in which these sweet solutions are mixed on site are by no means sterile, and the human traffic in the preparation environment increases an already substantial risk of contamination. Cross

contamination between patients is also a problem, as doses of solution may be given to more than one patient from the same container.

Finally, even when sucrose is conventionally employed, formulations of the sweet solutions are not carefully controlled and, therefore, the desired results not always or even predictably achieved. Studies have indicated that the minimum concentration of sucrose needed to produce effective analgesia for procedural pain may be about 18%. Although such studies are not definitive, it has been established that too low a concentration of sucrose may not be efficacious. On the other hand, overly high dosages of sugars to infants are known to be detrimental.

It would thus be desirable to provide a technique for preparation and administration of sucrose solutions by clinicians in an effective manner and without the deficiencies attendant to conventional procedures.

BRIEF SUMMARY OF THE INVENTION

The present invention comprises a system, method and package for providing sucrose solutions to neonatal infants.

According to the present invention, a solution of sucrose and water is formulated with a percentage of about 10% to about 50% sucrose, the remainder of the solution comprising water. The solution is metered into a cup or other container for single patient use or dosage. The product is packed aseptically or post-process sterilized for safety and freshness, and leaves the preparation site in a sealed, sterile state. Multiple containers of packaged solution are boxed and shipped to the end user. At the site of usage, a container is opened and the solution administered prior to a painful or otherwise stressful procedure, for example by dipping a pacifier in the opened container or drawing a small volume of solution into a dropper or syringe, the solution then be administered orally.

Other features and advantages of the present invention will become apparent to those of skill in the art through a consideration of the ensuing description, the accompanying drawings, and the appended claims.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

In the drawings, which illustrate what is currently considered to be the best mode for carrying out the invention:

FIG. 1 is a side sectional elevation of a cup-like container holding a volume of analgesic solution according to the present invention;

FIG. 2 is a partially cut away perspective view of a plurality of the cup-like containers of FIG. 1 holding solution; and

FIG. 3 is a flow diagram of a method of preparing and administering the analgesic solution according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to FIG.1 of the drawings, a thermally-formed or injection-molded polymer container 10 in a cup shape defining a cavity 12 and having a peripheral flange 14 at the mouth 16 thereof is filled, by way of example only, with about 40 ml of solution 18. After introduction of solution 18 into cavity 12, a cover 20 of a polymer film, a metal foil, a metallized insulating film or other suitable material is applied over mouth 16 and sealed to peripheral flange 14 by techniques known in the art. Peripheral flange 14 may have an annular indentation or groove in the top surface thereof as shown in broken lines 14a to facilitate cover 20 being sealed to peripheral flange 14 therealong by, for example, point contact with a heating tool. Cover 20 extends at least to an outer edge of peripheral flange 14. Container 10 as shown (see FIG. 2) is round, but other configurations such as square or rectangular with a like-shaped cover are contemplated. Suitable labeling (not shown) may be applied to the top of cover 20, as desired, for ease of viewing by the user.

Solution 18 may comprise a sucrose and water solution in the range of about 10% to about 50% sucrose, the remainder of the solution comprising water. The sucrose may be USP grade or clean sucrose, and the water clean or sterile. It is preferred currently by the inventor that solution 18 comprise about 24% USP grade liquid sucrose to about 76% clean water.

As noted above, the formulation and packaging of solution 18 may be performed aseptically or sterilization may be effected as a post process operation. Gamma

irradiation is contemplated as one suitable post process sterilization technique. The manner of preparing and packaging analgesic solution 18 according to the invention is known to those of ordinary skill in the relevant art, and so no further explanation thereof is deemed necessary.

FIG. 2 shows a plurality of sealed, cup-like containers 10 disposed in a box 30 for shipping. In the example shown, five groups of ten containers 10 each are layered in box 30 with spacer sheets 32 disposed between each layer, under the bottom layer and over the top layer. It may also be more easily seen from FIG. 2 that covers 20 of containers 10 includes integral protrusions or tabs 22 extending substantially beyond the outer extent of peripheral flanges 14 at one side thereof, the remaining periphery of covers 20 substantially following the outer extent of flanges 14. If desired, flanges 14 may also include a tab or protrusion 14b of similar shape to protrusion or tab 22 as shown in broken lines in FIG. 1 to protect protrusion 22 from inadvertent lifting during handling and shipping. Protrusion 22 enables gripping by the user to facilitate peeling the cover 20 off of container 10 for access to solution 18 in cavity through the wide mouth 16 as shown in broken lines. The relatively shallow depth and wide mouth configuration of container 10 is particularly advantageous for dipping of a pacifier end therein to coat it with solution 18 prior to insertion in an infant's mouth for the infant to suck. It may desirable to configure container 10 as even wider and shallower than as currently depicted in the drawings, to prevent tipping thereof if a pacifier is left therein between dosings. Similarly, the exemplary 40 ml volume of solution 18 in internal chamber 12 may be reduced to a lesser volume, for example 20 ml, as desired.

In accordance with the invention, it is preferred that a dose of no more than about 2 ml of solution 18 be administered to an infant for analgesia, approximately two minutes prior to a planned procedure. If a pacifier is employed, it may be dipped in analgesic solution 18 and inserted in the infant's mouth. In such an instance, a dose of solution 18 may comprise about 0.2 ml. Recoating of the pacifier should only be effected as needed, not to exceed administration of the aforementioned 2 ml of solution 18. If administered by syringe or dropper, a few drops of solution 18 may be applied to the tongue or buccal surface. A dose volume of 0.05 to 2 ml is preferred. Repeat doses of solution 18, which

may be administered during and immediately following the procedure, should not exceed the aforementioned 2 ml total volume. After the procedure, container 10 with residual solution 18 should be discarded to avoid any potential for cross contamination of other infants.

FIG. 3 comprises a flow diagram of an exemplary method of carrying out the present invention, comprising preparing the solution 18, packaging solution 18 in containers 10 either aseptically or with post process sterilization, boxing multiple containers 10 for shipment and shipping to a usage site (e.g., hospital), opening a container 10 in association with a planned procedure, administering the solution 18, and discarding any residual solution after the procedure. Of course, it would be possible to practice the invention by preparing solution 18 on site, packaging it aseptically and then using it on site. However, most if not all hospitals are equipped to perform a packaging operation as contemplated by the invention.

While the present invention has been described with respect to an illustrated embodiment, those of ordinary skill in the art will understand and appreciate that additions, deletions and modification to the illustrated embodiment are possible without departing from the scope of the invention as encompassed by the claims herein.